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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/408,578 09/29/99 HOLM

A P63882US0

EXAMINER

HM22/0718

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400 SEVENTH STREET NW
WASHINGTON DC 20004-2201

WESSENDORF, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/408,578

Applicant(s)

Holm et al

Examiner

T. Wessendorf

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- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 4/30/01

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above, claim(s) 16-42 and 45 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-6, 9-15, 43, and 44 is/are rejected.

7) ☒ Claim(s) 7 and 8 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

20) ☐ Other: _____

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Applicant's election with traverse of Group I, claims 1-18 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that Group II, e.g., claim 19 covers any product made by the method of claim 1, the only product that can be made according to the method of claim 1 is the product defined by claim 19. Thus, the method claims of Group I cannot be used to make a materially different product than the product defined in Group II. This is not found persuasive because as stated by applicants Group II covers any product obtainable by the process of claim 1 and would cover materially different products differing from one another in structure and possibly functions. Furthermore, the product of claim 19 can also be produced by other methods besides solid phase assembly e.g., solution phase or recombinant method.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-42, 45 are withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention and species (claims 16-18), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

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The disclosure is objected to because of the following informalities: "us of " at page 6, line 13 is recited twice.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The following phraseology: "enabling", "desired sequences", "if necessary", (e.g., claim 1); "if present", "and/or" (e.g., claim 2) fail to ascertain the claimed invention with precision.

B). The metes and bounds of the recited "mimics" thereof of each of the different compounds is indefinite.

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C). Claim 10 is indefinite in the recitation of "... At least one of the sequences is derived from a sequence..."

Claims 7-8 are objected to under 37 CAR 1.75© as being in improper form because a multiple dependent claim cannot depend on another claim. See MPEP § 608.01(n). Accordingly, the claims 7-8 have not been further treated on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Lange et al (J. Pept. Sci.) or 102(b) by Gilon et al (Pept. Chem. , Proc. Jpn. Symp.) Or (102b) by Mihara et al (J. Chem. Soc. Perkin Trans.)

Lange discloses a method of solid phase of peptide Bradykinin using a diaminodicarboxylic acid linker. See e.g., the abstract at page 289 and the detailed solid phase synthesis at e.g., page 90, Materials and Methods. The method of Lange using specific Bradykinin peptides with dicarboxylic linker fully

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meets the claimed method of solid phase of a ligand assembly, as broadly claim.

Gilon discloses a solid phase peptide synthesis using a dicarboxylic acid linker that links Arg with Gly to form a cyclic lactam ring. See e.g., e.g., page 482 up to page 483. The method of Gilon using specific peptides such as Substance P with dicarboxylic linker fully meets the claimed method.

Mihara et al discloses a solid phase peptide synthesis using a dicarboxylic acid anchor. See entire document specifically the Materials at page 1137. The method of Mihara using specific peptides with dicarboxylic anchor fully meets the claimed method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-6 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Mathiesen (WO 97/422210) and Tomalia et al (Angew. Chem. Intl. Ed. Engl.) in view of any one of Lange or Gilon or Mihara.

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Mathiesen discloses a method of making a peptide from a sequence of OspC of *Borelia burgforferi*. See e.g., the abstract. Tomalia similarly discloses the same method of making a peptide from OspC as Mathiesen. Each of these references does not teach cyclization of the linear OspC peptide. However, each of Lange, Gilon or Mathiesen discloses that cyclization using dicarboxylic linkers leads to a stable peptide. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to cyclize the linear peptide of each of Mathiesen or Tomalia using dicarboxylic acid as taught by e.g., Gilon since said cyclization results in a stable peptide. (Solid phase synthesis of peptide has advanced markedly that it is now automated).

No claim is allowed.

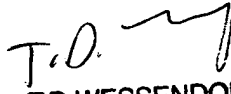
Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

tdw
7/1/301


T.D. WESSENDORF
PRIMARY EXAMINER